

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

IN RE: VALSARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:  
*All Actions*

Civ. No. 19-2875 (RBK/JS)

**CONFIDENTIALITY AND PROTECTIVE ORDER**

**WHEREAS** certain documents and information have been and will be requested, sought, produced, or exhibited by, between, and among the parties to the above- captioned action which involves the Valsartan products at issue and any future cases consolidated in this MDL (hereinafter "Action"), which relate to the parties' private proprietary information; trade secrets; proprietary scientific information; personal psychiatric, psychological, employment, and/ or medical information, and/ or other highly sensitive information, both business and personal; and,

**WHEREAS**, the Court finds that there is good cause for the entry of this Protective Order to protect "PROTECTED INFORMATION" from use in any manner inconsistent with this Protective Order;

**IT IS ON THIS \_\_ day of MAY, 2019 ORDERED THAT:**

**SCOPE OF PROTECTIVE ORDER**

This Confidentiality and Protective Order ("Protective Order") applies to all hard copy and electronic materials and other products of discovery, all information contained therein and derived therefrom and including, but not limited to, all copies, excerpts, summaries or compilations thereof, obtained by the Plaintiffs or Defendants pursuant to the

requirements of any court order, any requirements of self-executing discovery, discovery requests under the Federal Rules of Civil Procedure; documents subpoenaed under the Federal Rules of Civil Procedure, affidavits, certifications, or otherwise, and transcripts of depositions and/or non-public or in camera hearings (hereinafter "Discovery Material"), produced by any party to this proceeding (the "Producing Party") to any other party (the "Receiving Party"), or disclosed by the Parties in discovery, and/or produced by non-parties and designated pursuant to paragraphs 14 and 15 below, ~~and/or submitted to the Court in connection with a motion or hearing.~~ Confidential Information shall be used and disclosed only for purposes of proceedings in the Litigation not for any other purpose or function, except as otherwise provided herein.

1. This Protective Order is binding upon the parties to the Action, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys (including associates, assistants, paralegals and employees of counsel), agents, experts (whether testifying or consulting), consultants, ~~persons noticed or subpoenaed for deposition, actual or potential witnesses and their respective counsel, representatives, officers, directors, joint venturers, and employees as set forth in this Order, or any party hereto or who shall become a party to this litigation, unless modified by the Court.~~

2. Third parties may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and therefore become a Producing Party and/ or Receiving Party for purposes of this Protective Order.

3. Nothing herein shall be construed to affect or restrict in any manner the use or admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

4. This Protective Order is not intended to address or govern claims of privilege or work product that may otherwise be asserted by any of the parties, except to the extent provided in Paragraph 21 herein.

5. This Protective Order shall not be construed to protect from production or to permit the designation of any Discovery Material as "PROTECTED INFORMATION" that: the party (a) has failed to make reasonable efforts to keep confidential, (b) has lawfully obtained by or from another source, without breach of law, regulation, court order, or privilege, or (c) is at the time of production or disclosure, or subsequently becomes, through no wrongful act of the Receiving Party, readily accessible to others on a non-confidential basis. In the event the receiving party identifies any document it reasonably believes falls under this paragraph, it shall continue to treat the document as "PROTECTED INFORMATION" and follow the procedure set forth in Paragraph 20 of this Order.

6. Nothing in this Protective Order shall preclude any party or its representatives from inspecting, reviewing, using or disclosing its own "PROTECTED INFORMATION" in this litigation or in transactions or other matters unrelated to this case. To the extent the Designating Producing Party discloses any information previously designated as confidential, to another person or entity such that the information loses its confidential status, the Receiving Party is entitled to reasonably prompt notice that the information is no longer PROTECTED INFORMATION as defined in this Protective Order. No penalty shall accrue as a result of an inadvertent failure to do so.

7. Nothing shall prevent disclosure of "PROTECTED INFORMATION" beyond that required by this Protective Order if the Producing Party consents in writing to such disclosure.

8. This Protective Order does not relieve any party of its obligations to respond to discovery in the Action and shall not restrict or limit the Defendants in any way from complying with regulatory obligations.

**DEFINITIONS**

9. The following definitions shall apply to this Protective Order:

A. "Authoring Party" shall mean any Party or its counsel who authored, drafted, or otherwise created the Document(s) at issue.

B. The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law. Examples of such data protection laws include, without limitation: India's Information Technology Act, 2000; India's Information Technology Rules 2011. Plaintiffs shall be permitted to designate materials that contain confidential personal information, confidential prescription drug benefit-related documents and/or records; beneficiary-related documents; drug utilization data; regulatory, and commercial information; trade secrets; correspondence with regulatory bodies; research, technical, commercial or financial information that has been maintained as confidential, information and documents required to be kept confidential by law or by agreement with a third party; and other non-public sensitive or proprietary information as "CONFIDENTIAL".

INFORMATION" pursuant to this Order. NOTE: It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as "CONFIDENTIAL INFORMATION" in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions. The Court is confident that all parties and their counsel shall act in good faith at all times in making designations. Nonetheless, should it be demonstrated to the Court that a Producing Party has abused the discretion contemplated by the language of this paragraph and has unduly burdened their adversary, the Court shall entertain a petition for sanctions.

C. "Copies" shall mean any photocopies, reproductions, duplicates, extracts, summaries, notes, or descriptions of Documents and/or PROTECTED INFORMATION.

D. "Designating Party" shall mean any Party or its counsel or any other person who has designated the Document(s) at issue as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION pursuant to paragraph 13, below.

E. "Document(s)" shall be defined as they are in Federal Rule of Civil Procedure 34, whether produced or created by a Party or another person, and whether produced pursuant to the Federal Rules of Civil Procedure, Local Rules, subpoena, by agreement, or otherwise. This shall include, but not be restricted to, all interrogatory answers, responses to requests for production or for admission, deposition testimony, deposition exhibits, hearing testimony, hearing exhibits, trial exhibits, and trial transcripts.

F. "Final Adjudication" shall mean the entry of a final, non-appealable order disposing of the Litigation or an individual action that is or will in the future become a part thereof.

G. "Litigation" means the above-captioned litigation, including the Multi-District Litigation proceeding in the District of New Jersey, Case No. 1:19-md-02875, MDL No. 2875, and any individual cases direct filed in or transferred to the MDL.

H. "Party" shall mean a Party to this action, any employee of such Party, any counsel for such Party, and any paralegals or staff of counsel.

I. "Producing Party" shall mean any Party or its counsel or any other person who produced the Document(s) at issue.

J. "Product" means a Product at issue.

K. "PROTECTED INFORMATION" means Confidential Information and/or Restricted Confidential Information.

L. "Receiving Party" shall mean any Party or its counsel or any other person to whom PROTECTED INFORMATION is furnished.

M. "Restricted Confidential Information" means Documents that a Party has designated as "RESTRICTED CONFIDENTIAL" in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm; and Protected Health Information ("PHI"), as that phrase is defined in the Health Insurance Portability and Accessibility Act of 1996, Pub. L. 104-191 and the regulations promulgated

thereunder. TPP Plaintiffs may further designate as "RESTRICTED CONFIDENTIAL" contracts (including drafts) between a TPP Plaintiff and third parties, including any Pharmacy Benefits Manager, any other document or communication that contains or recites the terms of such a confidential contract, and any documents which contain research and analysis that is known by a TPP Plaintiff to be proprietary to any Pharmacy Benefits Manager, and all documents reviewed by or created by any Pharmaceutical and Therapeutics Committee of any health plan or pharmacy benefit manager. Any Documents designated as RESTRICTED CONFIDENTIAL shall only be disclosed to the Party's outside counsel and shall not be disclosed to any Party, a Party's witnesses, or in house counsel unless either a) the designating party explicitly agrees to the disclosure in writing, or b) a successful challenge is made and disclosure is ordered by the Court pursuant to paragraph 20, below, except that the designating party may disclose their RESTRICTED CONFIDENTIAL documents in connection with the litigation or during deposition subject to the requirements of paragraph 29, below.

10. The following shall not be designated as "PROTECTED INFORMATION":

- a. Documents of public record which are "readily accessible" as defined by Federal Law, or otherwise publicly available;
- b. Documents filed as a public record with the clerk of any federal or state court, not including exhibits or depositions or discovery responses which, if filed, were to have been filed under seal and with clear marking on the envelopes in which they are enclosed that they are subject to this Protective Order or a Protective Order entered in another case; [NOTE: Any exhibits, deposition transcripts or

discovery responses filed "under seal" shall remain PROTECTED INFORMATION.]

- c. Documents or articles published in trade magazines or other general circulation publications; or
- d. Documents previously provided to any individual or entity on a non-confidential basis, or readily accessible to third-parties on a non-confidential basis.

11. No items or information, including but not limited to summaries of items or information designated as "PROTECTED INFORMATION" shall be produced or disseminated orally, or by any other means, except as permitted by this Protective Order.

12. Any designation of "PROTECTED INFORMATION" under this Protective Order shall not be construed as an admission or an agreement by any party:

- a. That the designated disclosure constitutes or contains PROTECTED INFORMATION; or
- b. That any document, material or information, or any portion thereof, constitutes competent, material, relevant, or admissible evidence in this case.

**DESIGNATION OF "PROTECTED INFORMATION"**

13. Subject to the admonition of the Court stated in Paragraph 9 hereinabove, the Producing Party shall designate PROTECTED INFORMATION by marking "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" on the face of the document or material or, in the event that PROTECTED INFORMATION is produced electronically or natively,

on the disc or CD, on a placeholder document, and/or by such other means, including consistent with the ESI Protocol, so that the designation is communicated to the party receiving the document

14. **Notice of Designation of Non-Party Produced Documents.** Documents produced by a non-party must be treated by the receiving party as PROTECTED INFORMATION for a period of fourteen (14) days from receipt. In the event any non-party produces Documents or Information containing a Party's PROTECTED INFORMATION, that Party may designate such Documents or information, or portions thereof, as protected, pursuant to the provisions in paragraph 13 above, by providing notice of designation on all parties within fourteen (14) days of receipt.  
If a Party otherwise receives Documents authored by a Party to the Litigation, from any source other than the Party who, upon reasonable and good faith inquiry, appears to have authored or created the Documents (i.e. the Authoring Party), the Receiving Party will notify the Authoring Party in writing within ten (10) days of receipt of the Documents. The notification shall include: (1) the Bates numbers of the Documents received; (2) a brief description of the Documents; (3) the date received; and (4) the source of the Documents.  
Provided that such Documents are not publicly available, to the extent they contain PROTECTED INFORMATION but are not designated as such, the Authoring Party shall have the right to designate any such Document, or a portion thereof, as protected, pursuant to the provisions in paragraph 13 below.  
This provision is not intended to abrogate a party's work product privilege, and a

party may delay disclosure to an Authoring Party pursuant to this provision unless and until such documents are disclosed for use in the litigation, while treating the documents as PROTECTED INFORMATION during such period of non-disclosure.

15. **Non-Party Requests for PROTECTED INFORMATION:** Any Party to whom PROTECTED INFORMATION has been furnished who receives from any non-party (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards or associations) a subpoena or other process that seeks production or disclosure of such PROTECTED INFORMATION shall promptly, and in any case within three business days, give written notice by e-mail to counsel for the Designating Party so that the Designating Party may have adequate time before the Documents are to be produced to act pursuant to this Protective Order to guard against the disclosure of PROTECTED INFORMATION. The written email notice shall identify the Documents sought and the return date of the subpoena or other process, and the written notice shall also include a copy of the subpoena or other process. The Party receiving the subpoena shall also inform the person seeking the PROTECTED INFORMATION that such information is subject to this Protective Order. No production or other disclosure of such information pursuant to the subpoena or other process shall occur before the Designating Party approves the disclosure in writing or a Court order is issued on a timely filed motion to quash subpoena.

16. **Additional Parties:** If additional parties are added to this Litigation, then their or their counsel's ability to receive PROTECTED INFORMATION as set forth in this Protective Order will be subject to them or their counsel being bound by a written agreement or Court Order, to this Protective Order.

17. Subject to the admonition of the Court stated in Paragraph 9 hereinabove, all Documents and Copies produced or generated in this action pursuant to the discovery provisions of the Federal Rules of Civil Procedure, the Local Rules for the District of New Jersey, by order of this Court, or otherwise, and which contain, describe, identify or refer to PROTECTED INFORMATION shall be subject to the provisions of this Protective Order. Any Party shall have the right to designate, prior to production, any Documents or portion thereof, as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION pursuant to the following procedures:

A. **Documents.** For Documents in hardcopy form or in a modifiable electronic format: by affixing the following legend or stamp to each page of the Documents, or portion thereof, that is deemed "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" in such a way so as not to obscure any part of the text or content, so that the designation is communicated to the party receiving the document. For electronically stored Documents (other than Documents in a modifiable electronic form): by affixing the following legend or stamp to the cover letter referring to such electronically stored Documents and, to the extent possible, to the media (i.e., disc, hard drive, etc.) on which the Documents are provided: "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" or "RESTRICTED CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER," consistent with the ESI Protocol, so that the designation is communicated to the party receiving the document.

Whenever any Party to whom electronically stored Documents designated as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION are produced reduces such Documents to hardcopy form, that Party shall designate the hardcopy Documents with the legend or stamp as provided below in paragraph 18.

B. Transcripts. All portions of any deposition-hearing or trial transcript taken in the Litigation, wherein the Documents themselves, or the contents of the Documents, designated as PROTECTED INFORMATION are identified, discussed, or disclosed, shall also be designated as PROTECTED INFORMATION and shall be subject to the terms of this Protective Order. Within thirty (30) days after receiving a transcript, a Party may designate pages of the transcript and/or exhibits, or parts thereof to assure the minimum designations as reasonable, as PROTECTED INFORMATION by giving notice to all parties of same. PROTECTED INFORMATION within the transcript may be designated by indicating the portions of the pages that are confidential and marking such pages with the appropriate legend pursuant to the provisions above. Until expiration of the 30-day period, the entire transcript will be treated as RESTRICTED CONFIDENTIAL INFORMATION subject to protection against disclosure under this Protective Order.

An exhibit to a deposition shall be treated in accordance with any confidentiality designation or redaction previously given to it, and if not previously designated PROTECTED INFORMATION, then according to the designation later applied under this paragraph.

If no party or deponent timely designates PROTECTED INFORMATION in a transcript, none of the transcript will be treated as confidential. If a timely designation is made, the portions and exhibits designated shall be filed only under provisional seal, separate from the

portions and exhibits not so designated, and all Copies of the portions and exhibits so designated shall be treated as PROTECTED INFORMATION pursuant to the terms of this Protective Order. If any Party in good faith disagrees with a designation of any portion of a transcript or of any exhibit thereto as containing PROTECTED INFORMATION, the procedures regarding Challenges set forth in this Protective Order will govern.

18. **"CONFIDENTIAL INFORMATION/RESTRICTED CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER"**

Any Discovery Material for which it is impracticable or impossible to affix such a legend may be designated by written notice to that effect with a reasonable description of the material in question, and by designation on slip sheets where applicable. Such stamping or marking shall take place prior to, or contemporaneously with, the production by the Producing Party, or subsequent to the selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such a manner as not to obliterate or obscure any written matter. The stamp need not be affixed to every page of a multi- page document.

Inadvertent production of any document or information without a designation of "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" will not be deemed to waive a later claim to its protected nature or preclude a party from designating said document or information as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" pursuant to this Order at a later date, provided this is done within a reasonable time after production. Any party may designate as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" or withdraw "CONFIDENTIAL INFORMATION" or

"RESTRICTED CONFIDENTIAL INFORMATION" designation from any material that it has produced. A party must treat such documents and things with the noticed level of protection from the date such notice is received. A Party shall not be deemed to have waived any right to designate materials by allowing inspection of such materials prior to a designation. Such re-designation shall be accomplished by promptly notifying counsel for each party in writing of such re- designation. Upon production by the Designating Party of a set of the Documents containing PROTECTED INFORMATION marked CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION, the Receiving Party shall reasonably promptly destroy the previously produced undesignated Documents or information. Upon receipt of any re-designation and replacement image that designates material as "CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER" or "RESTRICTED CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER," all Parties shall (1) treat such material in accordance with this Protective Order; (2) take reasonable steps to notify any persons known to have possession of any such material of such re-designation under this Protective Order; and (3) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order, to the extent not already disseminated publicly.

19. Prior to producing documents that contain the names of patients other than Plaintiffs and/ or the physicians of such patients or consumers, the Producing Party may redact or delete the names, addresses, telephone numbers, social security numbers, and other information that would identify patients, research subjects and physicians or others constituting voluntary reporters or any other person associated with an adverse event, and any other

information required to be withheld from disclosure by 21 C.F.R. § 20.63, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and related regulations, applicable federal and state privacy laws, and other applicable laws and regulations.

The Producing Party may redact information contained in adverse event reports, consumer complaints, clinical studies, and other similar Documents, including names and any information that would identify the person (other than a plaintiff or plaintiff's decedent) using the Product; names and any information that would identify any third party involved with the report, including, but not limited to, a physician or hospital or other institution; and personnel information that is not relevant to the issues in the litigation. If the Producing Party produces copies of documents containing the names or other personal information of patients other than Plaintiffs or their physicians that is protected from disclosure pursuant to 21 C.F.R. § 20.63, HIPAA, or other governmental statute, rule or regulation, neither the Parties nor their counsel shall disclose the names or other personal information or contact any such patient or physician identified through the production of such documents. The prohibition does not apply, however, to information that was lawfully obtained through sources independent from the Producing Party's discovery productions. Nothing in this Section shall be construed to affect a Party's ability to redact irrelevant and/or non-responsive information from a Document, including information regarding other products or medications not at issue in this litigation.

20. A Party shall not be obligated to challenge the propriety of a "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" designation at the time made, and failure to do so shall not preclude a subsequent challenge thereto. However, in the event a Receiving Party who receives documents or information designated as "objects to such designation of" CONFIDENTIAL

INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" ~~objects to such designation of any or all of such items~~, the following procedure shall apply:

- (a) Counsel for the objecting party shall serve on the Producing Party or third party a written objection to such designation ~~within fifteen (15) days of receipt of such a designation~~, which shall describe with particularity the documents or information in question and shall state the grounds for objection. ~~Upon the Designating Party's receipt of written notification, the parties will confer in an effort to resolve the dispute without Court intervention. If, after conferring, the parties cannot resolve the dispute, either Party may make written application to this Court for a determination as to the appropriateness of the confidentiality designation. The written application shall describe with specificity the particular documents for which the designation is being challenged and set forth with specificity any and all grounds for the challenge. The Parties agree that the proponent of confidentiality or restricted confidentiality bears the burden of proof as to such designation. All documents or portions thereof designated as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION shall continue to be treated as such and subject to the terms of this Protective Order pending final determination of any such challenge and any and all proceedings or interlocutory appeals challenging such decision have been concluded.~~ Counsel for the Producing Party or third party shall respond in writing to such objection within fourteen (14) days of receiving the written

objection, and shall state with particularity the grounds for asserting that  
the document or information is CONFIDENTIAL or ATTORNEYS' EYES  
ONLY. If no timely written response is made to the objection, the  
challenged designation will be deemed to be void. If the Producing Party  
or third party makes a timely response to such objection asserting the  
propriety of the designation, counsel shall then confer in good faith within  
fourteen (14) days of the date when the Producing Party's written response  
is dated in an effort to resolve the dispute.

(b) If a dispute as to a "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a)(1), within twenty-one (21) days of the date when the Producing Party's written response is dated before filing a formal motion for an order regarding the challenged designation. Failure to request said conference, or to file the motion shall operate as a waiver of the disputed designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute. These time frames may be modified for good cause for specific challenges on informal application to the Court.

21. Inadvertent production of documents or information (hereinafter "Inadvertently Produced Documents") subject to the attorney-client privilege, the work-

product privilege or other legal privilege or doctrine protecting information from discovery shall not constitute a waiver of the privilege or doctrine, provided that the Producing Party shall notify the Receiving Party in writing of such inadvertent production as soon as is practicable after discovery of the inadvertent production. In that event, such Inadvertently Produced Documents and all copies thereof shall be returned to the Producing Party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database, except as set forth below. No use shall be made of such documents during depositions or at any hearing or trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. If the party receiving the Inadvertently Produced Documents disputes the claim of privilege, work product, or other statutory or court-ordered protection, it shall promptly notify the Producing Party. In the event the parties are unable to resolve the dispute, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the designated Documents are rightfully subject to a lawfully recognized privilege. In the event the Court resolves the dispute, either Party may petition the Court via formal Notice of Motion within ten (10) days from the date of the conference call; otherwise the Court's resolution of the issue shall stand. In the event the Court does not resolve the issue, the Producing Party may petition the Court to maintain the asserted privilege or protection, within ten (10) days from the date of the conference call; otherwise the claim of privilege or protection shall be deemed withdrawn. Counsel for the Receiving Party may retain one copy of the inadvertently produced document(s) for purposes of opposing the motion and may submit the document for in camera

review by the Court in connection with the motion. If the claimed privilege or protection is upheld or the challenge is waived, the document(s), along with any notes or other work product of the Receiving Party regarding the contents of such document(s), shall be destroyed or returned to the Producing Party.

This Paragraph is intended to comply with Federal Rule of Evidence 502(d) and (e), and shall not limit the protections of attorney-client communications and work product provided by Federal Rule of Evidence 502. Inadvertent production of Documents and information subject to work product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery ("Privileged Materials"), shall not constitute a waiver of the immunity or privilege. The Party discovering the inadvertent production shall notify in writing all Receiving Parties of the Privileged Materials within ten (10) business days of discovery. The Receiving Parties in possession of the Privileged Materials shall return them to the Producing Party, including any Copies of the Privileged Materials (except that Copies bearing handwritten or other notations made by the recipient, or work product reflecting the content of such materials, may be destroyed). Alternatively, upon request of the Producing Party, the Privileged Materials may be destroyed. In either event, all Privileged Materials shall be deleted from any litigation support and the Receiving Parties' databases. If, before being notified of the claim of privilege, a Receiving Party has already disclosed the Privileged Materials to others, the Receiving Party must take reasonable steps to retrieve the information or ensure that those to whom the information was disclosed, promptly destroy the Privileged Materials and any Copies.

If, however, a Receiving Party of the Privileged Materials believes that the Privileged Materials are not subject to the protection of the claimed privilege or doctrine,

**Commented [AS1]:** Plaintiffs believe that this paragraph should end here. The balance duplicates the procedures set forth above but with conflicting deadlines, thus duplicative and confusing.

that Party shall inform counsel for the Producing Party in writing of said challenge within seven (7) days of being notified of the inadvertent production in an attempt to resolve the challenge. If, after conferring, the Parties cannot resolve the dispute, the Party challenging the claimed privilege may request of the Court, within fourteen (14) days of being notified of the inadvertent production, an in camera review of the Privileged Materials in question.

The Privileged Materials shall not be used during depositions or at hearing or trial, and shall not be disclosed to anyone who was not given access to them before the request to return or destroy, unless the Receiving Party applies for, and later obtains, a Court Order denying the claimed privilege or protection.

**Commented [GT2]:** Defendants propose that the language in these two paragraphs be used rather than the language contained in the first paragraph, above.

#### **LIMITATIONS ON DISCLOSURE OF "PROTECTED INFORMATION"**

22. The parties agree that CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION Documents and information shall not be used by any person receiving CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION Documents and information for any business or competitive purpose and shall be used solely for purposes of this Litigation only and for no other action (litigation, arbitration, mediation, or other proceeding of any type) or purpose whatsoever (including, but not limited to, business, governmental, commercial, administrative, or judicial proceedings).. Except as allowed pursuant to paragraph 24 below, the Documents designated CONFIDENTIAL shall not, without leave of this Court, be disclosed to any person or entity other than this Court (under seal) and the Parties to this action and their counsel. The Documents designated RESTRICTED CONFIDENTIAL shall not, without leave of this Court, be disclosed to any person or entity other than this Court (filed under seal in accordance with

Local Rule 5.3) and the Receiving Parties' external litigation counsel and the Disclosing Party and its counsel.

23. All persons receiving or given access to "PROTECTED INFORMATION" in accordance with the terms of this Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Protective Order and determining a remedy for a breach of the Protective Order.

24. "CONFIDENTIAL INFORMATION" shall not be disclosed to anyone other than the following categories of persons:

- a. The Court (and any appellate court), including court personnel and any court-appointed special master;
- b. Mediators, secretaries, paraprofessional assistants, and other employees of such mediators who are actively engaged in assisting the mediators in connection with this matter;
- c. Employees of counsel for Plaintiffs or Defendants who have responsibility for assisting in the preparation and trial of this action or any appeal herein to the extent reasonably necessary to render professional services in this lawsuit.
- d. Employees of outside copying, document imaging, litigation and trial support, and facsimile services to the extent reasonably necessary to render professional services in this lawsuit;
- e. The persons who authored or contributed to the preparation of the "CONFIDENTIAL INFORMATION";
- f. Disclosure may be made to consultants or experts (hereinafter,

"consultants/experts") employed by Plaintiffs or Defendants, or their counsel, to assist in the preparation and trial of this litigation. However, prior to disclosure to any consultant/expert (including undisclosed consulting experts), the consultants/ experts must agree to be bound by the terms of this Protective Order by executing the acknowledgement annexed hereto as Exhibit "A". A copy of each executed acknowledgement shall be maintained for Plaintiffs' consultants// experts by Plaintiffs' Counsel, and for Defendants' consultants/ experts by Counsel for Defendants during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel for Producing Party that it will seek to have any documents designated as "CONFIDENTIAL INFORMATION" that were provided to consultants/ experts returned to counsel for the Receiving Party.

- g. In no event shall a Receiving Party make disclosure to litigation consultants/ experts who are serving or have served as non-litigation consultants, employees, officers, or directors of any competitors of Defendants, or anyone who at the time of disclosure is anticipated to become a non-litigation consultant, employee, officer, or director of any competitor of Defendants, except pursuant to the terms of this provision. In the event a Receiving Party wishes to make disclosure to any such litigation consultant/ expert, or to anyone

who at the time of disclosure, is anticipated to become such litigation consultant/ expert, irrespective of whether they are retained as a consultant/ expert for Plaintiffs, the parties shall "meet and confer" to determine a method to address such proposed disclosure. If, after meeting and conferring, the Parties are unable to agree on a method to address such proposed disclosure, either Party may contact the Court for the scheduling of a telephone conference call for the Court to determine whether and under what circumstances such disclosure by the Receiving Party will be permitted. The Court may conduct an *in camera* review of the documents at issue, in its discretion. The Court's determination on these issues shall be binding on all Parties. Prior to a determination by the Court on these issues, the Receiving Party may not disclose any CONFIDENTIAL INFORMATION to the proposed litigation consultant/ expert. A "competitor" shall be defined as an entity who is in the same business or commercial stream as the designating party, whether a pharmaceutical manufacturer or other company involved in the manufacturing, distribution, sale or marketing of Angiotensin Receptor Blockers or otherwise. Counsel for the Party who produced the subject CONFIDENTIAL INFORMATION shall be notified at least fourteen (14) days prior to disclosure to any person known to be an employee or agent of, non-litigation consultant to, any competitor of the Party whose designated documents are sought to be disclosed. Such notice shall provide a

reasonable description of the person, and their affiliation with the competitor, to whom disclosure is to be made, sufficient to permit objections to be made. If a Party objects in writing to such disclosures within fourteen (14) days of receipt of notice, no disclosure shall be made until the Party seeking to make the disclosure obtains prior approval of the Court or the objecting Party.

- h. The Parties to the extent required for assisting in the preparation and trial of each individual case or any appeal herein. To the extent such disclosure is made, such Party shall be advised of, shall become subject to, and shall agree in advance of disclosure to, the provisions of this Protective Order requiring that the material and information be held as protected.
- i. Deponents, Court reporters, videographers and their support personnel. Documents designated as "CONFIDENTIAL INFORMATION" may be shown to deponents during the deposition, but the deponent may not retain a copy of the document or have a copy of the transcript where the documents are discussed unless they have been informed of this Protective Order and has agreed in writing to be bound by it by executing Exhibit A to this Order.

25. All parties and their respective counsel, paralegals and employees and assistants of all counsel receiving Discovery Material, as well as any other individuals permitted to receive PROTECTED INFORMATION under any provision of this Protective

Order, shall take all steps reasonably necessary to prevent disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order.

26. Disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order may subject the disclosing person to such sanctions and remedies as this Court may deem appropriate.

27. No "PROTECTED INFORMATION" shall be made or delivered to any person other than those categories of persons referred to in Paragraph 24 above.

28. "PROTECTED INFORMATION" may only be disclosed to persons who are not included in those categories referred to in Paragraph 24, above, upon prior written consent of the Producing Party's counsel. If the Producing Party's Counsel refuses to give consent, the "PROTECTED INFORMATION" shall not be disclosed. The party requesting disclosure may apply to the Court via the procedure provided at Paragraph 20.

29. ~~Before PROTECTED INFORMATION is disclosed to any deponent or trial witness, counsel for the Producing Party should indicate on the record that testimony to be given regarding the Documents is subject to the terms of this Protective Order and deponent shall be required to acknowledge on the record, before any identification, discussion or disclosure of the Documents occurs that he or she has been advised of and has agreed to be bound by the terms of this Protective Order.~~ In the event that any question is asked at a deposition or non-public or in camera hearing, which a party asserts calls for "PROTECTED INFORMATION", or a document containing "PROTECTED INFORMATION" is identified as an exhibit in testimony given in this action, such question shall nevertheless be answered by the witness fully and completely to the extent required by law. While a witness is being examined about any PROTECTED INFORMATION, persons to whom disclosure is not authorized under

this Protective Order may be excluded from being present by the Producing Party or its authorized designee, unless there is a legal basis to preclude exclusion. In the case of deposition or other non-public or in camera hearing testimony, or any exhibit thereto, the transcript, video or exhibit, or portions thereof, as applicable, may be designated as "PROTECTED INFORMATION" in accordance with this Protective Order by notifying the other party:

(1) on the record, at the time of the testimony; or  
(2) in writing within twenty (20) days after the transcript has been received by counsel making the designation, specifying the testimony being designated protected by page and line number(s). Until the expiration of such 20-day period, the entire text of the deposition transcript, including all testimony therein, shall be treated as RESTRICTED CONFIDENTIAL INFORMATION under this Protective Order.

The court reporter shall mark the face of the transcript with the label set forth in Paragraph 18 of this Order. Any court reporter or transcriber who reports or transcribes testimony in this case shall be informed before the beginning of the deposition or non-public or in camera hearing about this Protective Order and shall be asked to take reasonable and appropriate steps to preserve RESTRICTED CONFIDENTIAL INFORMATION. It is the obligation of the Producing Party to make any application to the Court with respect to the provisions of this paragraph. Should there develop any conflict between the timing provisions set forth in this Paragraph and the timing provisions regarding motion procedures set forth in Paragraph 31, below, Paragraph 31 shall prevail.

30. If a party receiving "PROTECTED INFORMATION" in accordance with the terms of this Protective Order is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for the

production of any "PROTECTED INFORMATION" produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until ten (10) business days after notifying counsel for the Producing Party in writing of the following: (a) the information and documents that are sought by the subpoena; (b) the date on which compliance with the subpoena is requested; (c) the location at which compliance with the subpoena is requested; (d) the identity of the party serving the subpoena; (e) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. The party receiving the subpoena or other process shall cooperate with the Producing Party in any proceeding relating thereto.

**COURT SUBMISSIONS CONTAINING "PROTECTED INFORMATION"**

31. Any documents that a Party wishes to file with the Court during this Action which have previously been designated as "PROTECTED INFORMATION" (or which contain CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION), and all pleadings and memoranda purporting to reproduce or paraphrase such "PROTECTED INFORMATION," shall be filed in a manner that preserves the confidentiality of such information. To the extent possible, parties shall attempt to avoid the need to file materials under seal by working with the Producing Party to create non-confidential, redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to filings. Where the filing party has not had an opportunity to confer with the Producing Party, in advance of a filing, the filing party shall not attach

materials containing "PROTECTED INFORMATION" to its filing but shall instead designate by Bates number the materials containing "PROTECTED INFORMATION" that would have been attached or completely redact all "PROTECTED INFORMATION" from such materials. No otherwise timely filing shall be considered late or incomplete if the filing attaches Bates numbers or redacted documents in place of materials containing "PROTECTED INFORMATION." Within ten (10) business days of the filing, the filing party and Producing Party shall confer to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to the filing in place of the Bates number designations or redacted materials. If the parties are unable to reach an agreement, then the designating party, the Producing Party, must file a motion to seal the materials containing "PROTECTED INFORMATION" pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the filing of the original motion, or else waive confidentiality as to the materials containing "PROTECTED INFORMATION" at issue. If the Producing Party waives confidentiality as to the materials at issue, the filing party may replace the Bates number designations or redacted materials with the full text of the documents at issue.

**Commented [GT3]:** The parties agree to discuss this provision with the Court.

32. If "PROTECTED INFORMATION" is filed under seal pursuant to the procedure established by Paragraph 31, and is ordered by the Court to be maintained under seal, the "PROTECTED INFORMATION" and/ or other papers shall be kept under seal until further order of the Court. However, said "PROTECTED INFORMATION" and other papers filed under seal shall only be available to the Court and counsel of record.

#### **MISCELLANEOUS PROVISIONS**

33. This Protective Order may be amended with leave of Court, or by the agreement of counsel for the parties in the form of a stipulation submitted to the Court for approval. If the parties cannot agree to an amendment, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the requested amendment is appropriate. In the event said conference call does not resolve the question to both sides' satisfaction, either may petition the Court via formal Notice of Motion. This Protective Order is intended to regulate the handling of "PROTECTED INFORMATION" during this litigation, but shall remain in full force and effect until modified, superseded or terminated on the record by agreement of the parties thereto or by order of the Court.

34. Within thirty (30) days of the final termination of this case, whether by judgment, settlement or otherwise, (or such other time as the Producing Party may agree in writing), the parties shall return all "PROTECTED INFORMATION" to counsel for the Producing Party, and all copies thereof in his/her possession or subject to his/her control (including but not limited to materials furnished to consultants and/ or experts), or shall certify to counsel for the Producing Party that all such Discovery Material has been destroyed. Outside counsel shall not, however, be required to return or destroy any pleadings, pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business, which records will continue to be maintained as "PROTECTED INFORMATION" in conformity with this Protective Order.

35. All rights available at law are reserved for any violation of this agreement.

36. **Applicability**

A. Generally. This Protective Order shall be binding throughout and after Final Adjudication of this action, including but not limited to, Final Adjudication of any appeals and petitions for extraordinary writs.

B. Waiver. Any Party may expressly waive in writing the applicability of any provision of this Protective Order to any Documents or portions thereof that the Party produces, or may effectuate a waiver pursuant to the terms of this Order. Such waiver shall apply only to the Documents or portions thereof to which the applicability of the specified provision of this Order is expressly waived.

D. Effective Date. This Protective Order shall become effective and binding upon each of the Parties and their undersigned counsel on the date the Court approves and enters this Protective Order.

E. Violation. Any violation of this Protective Order by any Party or person to whom PROTECTED INFORMATION is disclosed pursuant to the terms of this Protective Order shall constitute contempt of court and be punishable as such, and shall subject the offending Party or person to such additional and further remedies as may be available to the aggrieved Party.

If PROTECTED INFORMATION is disclosed in violation of this Protective Order, whether inadvertently or otherwise, the Party responsible for the disclosure shall use reasonable efforts to bind the recipient to the terms of this Protective Order, and shall (a) promptly inform the recipient of the terms of this Protective Order, (b) request the return of the PROTECTED INFORMATION and all Copies, and the destruction of work product and other materials reflecting the PROTECTED INFORMATION, and (c) request that the recipient sign a Declaration in the form of Exhibit A. If the recipient does not agree to sign a Declaration, the

Party responsible for the disclosure shall identify the recipient immediately to the Party designating the PROTECTED INFORMATION.

G. Nothing in this Protective Order shall be construed to limit a Party's right to disclose to any person or use its own information or Documents including its own PROTECTED INFORMATION for any purpose.

H. Nothing in this Protective Order shall prevent a Party from using or disclosing information, including PROTECTED INFORMATION, obtained through discovery as necessary to meet reporting obligations to the F.D.A. or any governmental agency.

**37. Procedure Following Final Adjudication**

Within thirty (30) days after Final Adjudication of all cases within the Litigation:

1. The Clerk of Court shall maintain or dispose of all Documents filed under seal and designated as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION including, without limitation, all transcripts or other things which were subject to the provisions of this Protective Order in accordance with the Federal Rules of Civil Procedure as well as the local rules of the District of New Jersey and any applicable orders regarding maintenance or disposal of sealed documents;
2. Parties and counsel having possession, custody or control of such Documents, transcripts, or other things designated CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION shall completely destroy or return to counsel for the Producing Party, at the election of the Producing Party, the PROTECTED

INFORMATION, except that Plaintiffs' counsel having multiple cases in the Litigation may fulfill these obligations after Final Adjudication of their last remaining case. This includes an obligation on the part of a Party to obtain and either return or destroy, at the election of the Producing Party, all such PROTECTED INFORMATION previously provided to outside experts and consultants and others who executed Exhibit A. Upon receipt of a written request for verification, counsel shall provide, within thirty days, a written verification of his or her destruction or return of the PROTECTED INFORMATION.

**38. Protective Order Not Admissible**

This Protective Order, including any discussion of the procedures and provisions herein, shall not be admissible in evidence. Counsel for a Party shall not, in the presence of the jury, comment on the Protective Order nor comment on the reasons or motivation for designating the Documents as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION without first having obtained permission of the Court to do so.

**39. Amendment**

The parties reserve the right to move the court for an order to amend or to set aside this Protective Order, in whole or in part, upon good cause shown.

SO ORDERED, this. \_\_\_\_ day of April, 2019

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HON. ROBERT B. KUGLER

**EXHIBITA**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

*All Actions*

Civ. No. 19-2875 (RBK/JS)

**ACKNOWLEDGMENT AND AGREEMENT TO  
BE BOUND BY PROTECTIVE ORDER**

The undersigned agrees:

I hereby attest to my understanding that the information or documents designated "PROTECTED INFORMATION" are provided to me subject to the Protective Order entered in In re Valsartan Products Liability Litigation, Docket No. 19-cv-2875, that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Acknowledgment and Agreement to be Bound by Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as protected pursuant to this Protective Order.

I further agree that I shall not disclose to others, except in accord with this Protective Order, any "PROTECTED INFORMATION", as defined therein, or any information contained in such "PROTECTED INFORMATION", in any form whatsoever, and that such "PROTECTED INFORMATION" and the information contained therein may

be used only for the purposes authorized by this Protective Order.

I further agree and attest to my understanding that my obligation to honor the protected nature of such "PROTECTED INFORMATION" will continue even after this litigation concludes.

I further agree that if I fail to abide by the terms of this Protective Order, I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for the purposes of any proceedings relating to enforcement of this Protective Order, and I specifically agree to subject myself to the jurisdiction of the United States District Court for the District of New Jersey for this purpose.

Date: ----- By: -----  
(Signature)

\_\_\_\_\_  
(Printed)

\_\_\_\_\_  
(Street Address)

\_\_\_\_\_  
(City, State and Zip Code)

\_\_\_\_\_  
(Telephone)